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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/869,334 | 09/26/2001 | Hirofumi Endo | P21289 | 5711 |
| 7055 | 7590 | 04/13/2004 | EXAMINER | |
| GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191 | | | RAMIREZ, DELIA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,334

Applicant(s)

ENDO ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>Alignment</u> |

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DETAILED ACTION

Status of the Application

Claims 1-39 are pending.

Applicant's preliminary amendment of claims 5-7, 17, 21, 24-28, 37 and 38 in a communication filed on 7/26/2001 is acknowledged.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn in part to a single protein from B. subtilis ATCC6051 which has the activity of producing compounds IIa or IIb.

Group II, claim(s) 1-6, drawn in part to a single protein from B. megaterium ATCC10778 which has the activity of producing compounds IIa or IIb.

Group III, claim(s) 1-6, drawn in part to a single protein from B. megaterium ATCC11562 which has the activity of producing compounds IIa or IIb.

Group IV, claim(s) 1-6, drawn in part to a single protein from B. megaterium ATCC13402 which has the activity of producing compounds IIa or IIb.

Group V, claim(s) 1-6, drawn in part to a single protein from B. megaterium ATCC15177 which has the activity of producing compounds IIa or IIb.

Group VI, claim(s) 1-6, drawn in part to a single protein from B. megaterium ATCC15450 which has the activity of producing compounds IIa or IIb.

Group VII, claim(s) 1-6, drawn in part to a single protein from B. megaterium ATCC19213 which has the activity of producing compounds IIa or IIb.

Group VIII, claim(s) 1-6, drawn in part to a single protein from B. megaterium IAM1032 which has the activity of producing compounds IIa or IIb.

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Group IX, claim(s) 1-6, drawn in part to a single protein from *B. laterosporus* ATCC4517 which has the activity of producing compounds IIa or IIb.

Group X, claim(s) 1-6, drawn in part to a single protein from *B. pumilus* FERM BP-2064 which has the activity of producing compounds IIa or IIb.

Group XI, claim(s) 1-6, drawn in part to a single protein from *B. badius* ATCC14574 which has the activity of producing compounds IIa or IIb.

Group XII, claim(s) 1-6, drawn in part to a single protein from *B. brevis* NRRL B-8029 which has the activity of producing compounds IIa or IIb.

Group XIII, claim(s) 1-6, drawn in part to a single protein from *B. alvei* ATCC6344 which has the activity of producing compounds IIa or IIb.

Group XIV, claim(s) 1-6, drawn in part to a single protein from *B. circulans* NTCT-2610 which has the activity of producing compounds IIa or IIb.

Group XV, claim(s) 1-6, drawn in part to a single protein from *B. macerans* NCIMB-9368 which has the activity of producing compounds IIa or IIb.

Group XVI, claim(s) 1-4, 7, drawn in part to a single protein from *B. sp.* FERM BP-6029 which has the activity of producing compounds IIa or IIb.

Group XVII, claim(s) 1-4, 7, drawn in part to a single protein from *B. sp.* FERM BP-6030 which has the activity of producing compounds IIa or IIb.

Group XVIII, claim(s) 1-5, drawn in part to a single protein from *B. sphaericus* which has the activity of producing compounds IIa or IIb.

Group XIX, claim(s) 1-5, drawn in part to a single protein from *B. stearothermophilus* which has the activity of producing compounds IIa or IIb.

Group XX, claim(s) 1-5, drawn in part to a single protein from *B. cereus* which has the activity of producing compounds IIa or IIb.

Group XXI, claim(s) 1-5, 8, drawn in part to the polypeptide of SEQ ID NO: 1

Group XXII, claim(s) 1-5, 9-13, drawn in part to the polypeptide of SEQ ID NO: 42.

Group XXIII, claim(s) 1-5, 9-13, drawn in part to the polypeptide of SEQ ID NO: 45.

Group XXIV, claim(s) 14, 21-39 drawn in part to the polynucleotide of SEQ ID NO: 2, vectors and host cells comprising said polynucleotide, a method for producing a compound using the host cells, and a method of recombinantly producing the corresponding polypeptide.

Group XXV, claim(s) 15-16, 18-20, 39, drawn in part to the polynucleotide of SEQ ID NO: 41.

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Group XXVI, claim(s) 15-16, 18-20, 39, drawn in part to the polynucleotide of SEQ ID NO: 43.

Group XXVII, claim(s) 15-16, 18-20, 39, drawn in part to the polynucleotide of SEQ ID NO: 44.

Group XXVIII, claim(s) 17, drawn in part to a single polynucleotide encoding a Bacillus protein which has the activity of producing compounds IIa or IIb.

2. The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The technical feature of Group XXI is the polypeptide of SEQ ID NO: 1, which is shown by Kunst et al. (GenBank accession number CAB13078, November 1997) to lack novelty or inventive step as Kunst et al. teaches a polypeptide which is 100% sequence identical to the polypeptide of SEQ ID NO: 2, and does not make it a contribution over the prior art.

4. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Although the polypeptides of Groups I-XXIII, and the polynucleotides of Groups XXIV-XXVIII share a common property within Groups I-XXIII and XXIV-XXVIII in that they are either nucleic acids or proteins, the compounds are not regarded as being of similar nature because all the alternatives do not share a common structure or function. It is noted that the specification is completely silent in regard to (1) the structures of all these polypeptides/polynucleotides, and (2) the biological function of the claimed polypeptides, e.g. specific enzyme type. The recitation of "has an activity of producing compound X from compound Y" is not sufficient to determine if the polypeptides claimed have the same biological

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function and a shared/common structure. Therefore, each of the polynucleotides/polypeptides of Groups I-XXIII and XXIV-XXVIII appear to encode/be proteins of diverse function and structure.

5. According to PCT Rule 13.2, unity of invention exists only when there is a share same or corresponding technical feature among the claimed inventions. Groups I-XXIII are directed to proteins which have the special technical feature of being polypeptides capable of producing compound X from compound Y. Groups XXIV-XXVIII are directed to nucleic acids which have the special technical feature of being polynucleotides which encode proteins capable of producing compound X from compound Y, not shared by Groups I-XXIII.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or

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relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 31, 2004


REBECCA E. PROULX
PRIMARY EXAMINER
GROUP 1800